

## Preclinical Development Awards

### RFA 14-02: CIRM Preclinical Development I Awards

The purpose of the CIRM Preclinical Development Initiative is to fund early preclinical development activities for Development Candidates (DCs) derived from or targeting stem cells that have compelling and reproducible efficacy in preclinical models of disease or injury, and that are sufficiently well characterized to be ready for the transition from preclinical research to preclinical development. Funding will be provided for the most promising, competitive and successful Development Candidates that CIRM has already invested in at the preclinical research stage, as well as for compelling new projects that are co-funded with matching funds.

The objective of this award is the conduct, within 30 months, of a well-prepared pre-IND meeting with the Food and Drug Administration (FDA), in which readiness to initiate IND-enabling pivotal studies is demonstrated.

This RFA will allow limited participation by members of CIRM's Collaborative Funding Partner (CFP) Program, specifically for projects in which the proposed Development Candidate was identified with support of prior funding from CIRM and a Collaborative Funding Partner.

Please see the RFA for full details.

#### RFA 14-02 Preclinical Development I

(Amended 5/9/14 - Section V.A on page 6 of the RFA was amended to make a correction on the list of ineligible therapeutic candidates.)

CIRM has conducted a **webinar** for prospective applicants on May 13, 2014 at 11:00 am PDT to address questions about the RFA and application process. The following materials can be viewed/listened to:

1. Presentation Slides
2. Session Recording
3. Q & A

#### Application Process

Submission of an application for this RFA involves a two-step process. Any eligible applicant may submit a single Letter of Intent (LOI). CIRM will use the LOI to confirm eligibility using the criteria described in the RFA. Applicants who fail to meet eligibility criteria will be notified by email. All others may submit a full Application.

#### Letter of Intent Submission Instructions

LOIs must be submitted online via the CIRM Grants Management Portal. Each PI may submit only a single LOI for this RFA. The deadline for submission is **5:00 p.m. (PDT) on June 5, 2014**. No exceptions to this deadline will be made.

To submit the LOI,

1. Go to the Grants Management Portal and log in with your existing CIRM Username and Password. If you do not have a Username, click on the **"New User"** link and follow the instructions to create a CIRM Username and password.

2. After logging in, click on the **"Menu"** tab. Select the link labeled **"Open Programs"**. Under the section labeled **"RFAs and Programs Open for Applications"**, click on the **"Start a Letter of Intent"** link located in the **"RFA 14-02 CIRM Preclinical Development I Awards"** section.
3. Select the Applicant Institution from the dropdown menu (or select "other" and enter the institution name if it is not listed.) Complete the LOI by following the posted instructions.
4. The **"Done with Letter of Intent"** button becomes enabled when all sections are complete. Select this button to complete your LOI submission. Once this button has been selected, you will no longer be able to make changes to your LOI.
5. To ensure the process is complete, click on the **"Menu"** tab and select **"Your Submitted Applications"** from the drop down list. Your submission for the **RFA 14-02 CIRM Preclinical Development I Awards: Letter of Intent** should appear in the table labeled **"Your Submitted Applications"**.

### Full Application Submission Instructions

Only those applicants who submitted an LOI that was accepted by CIRM may submit an application. Applicants who submitted an LOI but were not notified that they were ineligible will be able to submit a full application using application forms that will be available on the CIRM website in June. The application for this RFA will consist of up to six parts:

Part A: Application Information Form (web-based form)

Part B: Proposal (MS Word template)

Part C: Biographical Sketches (MS Word template)

Part D: Activity Based Budget (MS Excel template)

Part E: Licenses, Co-Funding and Material Transfer Agreements

Part F: Regulatory Correspondence

All parts of the application must be submitted no later than **5:00 p.m. PST on November 3, 2014** via the Grants Management Portal. It is the applicant's responsibility to meet this deadline; no exceptions will be made.

### Schedule of CIRM Deadlines and Reviews

Letters of Intent due	5:00 pm PDT, Thursday, June 5, 2014
Full Applications due	5:00 pm PST, November 3, 2014
Review of full Applications by Grants Working Group (GWG)	Q1, 2015
Review and Approval by ICOC	Q2, 2015
Earliest Funding of Awards	Q2/3, 2015

### Contacts:

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**ICOC approval:**

Mar 26, 2015

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